Research Article

Hang-up IUD, New Technique for Suturing CuT-380A IUD to Uterine Fundus in Immediate Postplacental Insertion during Cesarean Delivery: Twelve Months Follow up

Hang-up IUD, Teknik Baru Penjahitan IUD CuT-380A pada Fundus Uteri pada Insersi IUD Pascaplasenta Persalinan Bedah Sesar: Pemantauan Dua Belas Bulan

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Abstract

Objective: The aim of this study was to evaluate the effectiveness, side effects and acceptability of postplacental CuT-380A IUD insertion using new technique for suturing to uterine fundus during cesarean section (hang up technique).

Method: Prospective cohort study of postplacental IUD CuT-380A insertion during cesarean delivery. Hang-up technique consists of performing a puncture in the center of the fundus wall using straight needle into the uterine cavity and subsequently using chromic catgut no. 1 to tie the IUD using anchor knot and hanging the IUD to the fundus. Our subjects were women who underwent caesarean delivery at dr. Kariadi Hospital between 1st June 2009 to 31st April 2011 and followed up at <6 weeks, 6 weeks, 3 , 6, 9 and 12 months.

Result: From 116 women, 8 women (7.4%) were lost to follow-up. The 108 women were observed by scheduled home visits or by mail or telephone. The youngest patient was 15 years old and the oldest was 40 years old. The proportion of primiparous and multiparous women was comparable (49.1% and 50.9%), gestational age was 28-44 weeks, birth weight ranged 2,950-4,500 grams. Six weeks post cesarean section, out of the 108 women, two women complained of foul-smelling lochia, two had puerperal fever, and three complained of pelvic pain. At 6-months follow-up, 3 women underwent IUD removal because two found the string very disturbing and the other wanted to get pregnant because their child died. At 9-months post-cesarean one woman was reported to be pregnant with IUD in situ. At >12 months follow-up, one woman underwent IUD removal because of severe dysmenorrhea. No perforation or expulsion was reported.

Conclusion: Immediate postplacental insertion of IUD CuT-380A using hang-up technique is safe and effective. Typical use effectiveness is high (Pearl Index 0.93) and there were no reported incidents of expulsion or perforation. Acceptance and continuation rate were high, 98.15% and 95.37% respectively.

[Indones J Obstet Gynecol 2014; 2-31: 132-139]

Keywords: anchor knots, cesarean section, hang-up IUD, postplacental IUD insertion

Abstrak

Tujuan: Untuk mengevaluasi efektivitas, efek samping, faktor risiko dan tingkat penerimaan insersi IUD CuT-380A pascaplasenta menggunakan teknik baru untuk mengikatkan IUD pada dinding fundus uteri (teknik hang-up) pada persalinan bedah sesar.

Metode: Penelitian prospektif deskriptif dengan subjek penelitian yaitu semua wanita yang menjalani persalinan bedah sesar di RSUP Dr. Kariadi antara 1 Juni 2009 hingga 31 April 2011. Teknik hang-up dilakukan dengan menembuskan jarum melalui bagian tengah dinding fundus uteri memasuki kavum uteri, menggunakan benang kromik catgut no. 1 untuk mengikat IUD dengan simpul jangkar dan menggantungkan IUD pada fundus uteri. Pemantauan dilakukan pada periode <6 minggu pascapersalinan, <3 bulan, <6 bulan, <9 bulan, <12 bulan dan 12 bulan pascapersalinan.

Hasil: Di antara 116 akseptor, 108 akseptor dipantau melalui kunjungan rumah dan telepon, terdapat loss of follow-up pada 8 orang (7,4%). Akseptor termuda berusia 15 tahun dan yang tertua berusia 40 tahun. Proporsi sebanding untuk pasien primipara dan multipara (49,1% dan 50,9%), usia kehamilan berkisar antara 28-44 minggu, berat badan lahir berkisar 2.950-4.500 gram. Selama pemantauan 6 minggu pascabedah sesar, dari 108 akseptor, terdapat 2 akseptor dengan keluhan lokia berbau busuk, 2 akseptor dengan demam nifas dan 3 akseptor dengan keluhan nyeri panggul. Pada pemantauan 6 bulan, 3 akseptor menjalani pencabutan IUD dengan alasan benang IUD sangat mengganggu pada 2 akseptor dan 1 akseptor ingin hamil karena anak meninggal. Pada 9 bulan pascabedah sesar, 1 akseptor mengalami kehamilan dengan IUD in situ. Pada pemantauan >12 bulan, 1 akseptor menjalani pencabutan IUD karena dismenore berat. Tidak ada laporan kejadian perforasi atau ekspulsi.

Kesimpulan: Insersi IUD CuT-380A menggunakan teknik hang-up adalah aman dan efektif pada 12 bulan pemantauan. Efektivitas penggunaan tipikal cukup tinggi (Pearl index 0.93), dan tidak ada laporan kejadian ekspulsi maupun perforasi. Angka penerimaan dan kelangsungan pemakaian tinggi, masing-masing 98,15% dan 95,37%.

[Maj Obstet Ginekol Indones 2014; 2-3: 132-139]

Kata kunci: bedah sesar, insersi IUD pascaplasenta, simpul jangkar, teknik hang up

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INTRODUCTION

Intrauterine device (IUD) is the most widely used long-term contraceptive method in the world. There are more than 160 million IUD users world-

wide, mostly in China and India.^{1,2} Meanwhile, the use of IUDs in Indonesia has decreased. In 1991 the coverage rate of IUD use reached 13%, whereas the Indonesia Primary Health Survey in 2010

showed IUD users only reached 5%.3 Of all types of IUDs, Copper T-380A (CuT-380A) is most effective and has been recommended by WHO, with postpartum application being the flagship program of the National Family Planning and Population Board. 1,3,4-8 IUDs are safe, comfortable and effective. They can be inserted immediately after delivery (including immediately after delivery of the placenta), effective immediately after insertion, effectiveness lasts for up to 10 years, does not affect lactation and fertility recovery is immediate after IUD removal.^{2,4,5,9}

In the postpartum period, demographics and world health survey showed that very few women become pregnant again within 2 years after delivery (3%-8%), and 50-96% of women want to use contraceptives in the first year after childbirth. Moreover, of all postpartum women who wanted to use contraception, 40% of them did not do so for various reasons including lack of health care providers on postpartum care, including access to family planning. 10-12

A British study stated that of all mothers who have given birth, only 50% are discharged from the hospital with contraceptives, and only 4% of mothers had the opportunity to discuss postpartum contraception during the antenatal visit. 13 This data illustrates the lack of attention to postpartum contraceptive services. Since the postpartum period is a very appropriate period to start contraception, counseling and provision of appropriate information about contraception post-delivery, especially since antenatal visits, reinforced by motivating the couple to postpone pregnancy is very important.11

There are two ways IUD insertion, in the postpartum period (postplacental, immediate or early insertion, i.e. within a period of 48 hours up to 6 weeks postpartum) and after the puerperium (after puerperal or interval period).4,8,14 Immediate post-placental IUD insertion is insertion within 10 minutes after placenta delivery. Immediate postplacental IUD insertion is relatively more comfortable, safe and efficient as indicated by the presence of a high level of usage and low incidence of puerperal infection, bleeding problems or perforation.4,5

IUD insertion during cesarean section was first introduced in 1967 by Zerzavy by suturing the IUD to the posterior uterine fundus.¹⁵ Research in China and Belgium introduced postplacental IUD insertion technique during cesarean delivery with an IUD placed as high as possible in the fundus without suturing the fundus wall. Previous studies stated that IUD insertion during cesarean section is a safe and easy method. Possible side effects such as bleeding and infection are very rare, and the incidence of expulsion is lower than IUD insertion after vaginal delivery. Furthermore, there were no reported perforation incident. 16,17

In Indonesia, there have been no studies on postplacental IUD insertion during cesarean section. This study presents the effectiveness, side effects and acceptability of postplacental IUD insertion at cesarean delivery in the Department of Obstetrics and Gynecology, Faculty of Medicine Diponegoro University/Dr. Kariadi Hospital using new techniques introduced by Hary Tjahjanto in 2009 called 'hang-up IUD' technique.

METHOD

This study is a prospective cohort study of postplacental CuT-380A IUD insertion during cesarean section delivery. Subjects were all women who had cesarean section during the period of 1 June 2009 to 31 April 2010 and reached at least 100 acceptors in the first year of monitoring.

Inclusion criteria include all couples who were willing to undergo the study and signed an informed consent, agreed to come on scheduled control, and had cesarean section delivery. Exclusion criteria were women with sexually transmitted diseases/AIDS, genital tract malignancy and anatomic abnormalities of the uterus, uterine atony and the presence of intrauterine infection. IUD insertion was performed by the researcher and senior resident.

Hang up technique is done by penetration using needle until uterine cavum, anchor knot tying at crossing arm of CuT IUD reinforced with a simple knot, then the IUD is pulled so that the thread is at the uterine cavity entrance and the IUD is hung in the middle of the fundus and then a knot is made on the outside wall of fundus for fixation. The outline of insertion steps are as follows:

Straight needles and surgical thread (chromic catgut or PGA) are used. Needle is inserted perpendicularly from the outside to penetrate the median of the fundus wall to get into the uterine cavity. Once the surgical thread entered the uterine cavity, the needle is clamped with rings forceps and pulled

out through the lower uterine segment incision. Subsequently, an anchor knot is made on the crossing arm so that the IUD is balanced and hanging flexibly on the wall of the fundus. The IUD string is then cut in the middle of the long thread. Using ring forceps for clamping the IUD, it is inserted into the uterine cavity while simultaneously pulling the surgical thread out of the uterus so that the IUDs horizontal arm is attached to the middle uterine fundus wall. The position of IUD remains suspended by the thread. Then, a knot is made on the outer surface of the uterus so the IUD will be fixed and hangs from the fundus.

Subjects are observed on the scheduled one week after discharge from the hospital until <6 weeks after insertion (M-1/first monitoring), at 6 weeks until 3 months (M-2), at 3 months until 6 months (M-3), at 6 months until 9 months (M-4), at 9 months until 12 months (M-5) and 12 months or more after IUD insertion (M-6). Ultrasound examination was performed in the family planning clinic to determine the location of IUD and conducted by researchers and residents on duty. If the acceptor does not arrive on time, they will be invoked by mail or home visits. If they can not be contacted or found until the end of the study they will be considered as loss of follow-up. Data were recorded in a special form and analyzed descriptively.

RESULT

During the period of June 1 2009 until April 31 2011, the number of acceptors who had used IUD with hang-up technique insertion for 1 year or longer were 116 (20%) mothers out of the 577 women who underwent cesarean section. In monitoring conducted after 12 months post-insertion (M-6), the number of acceptors who can be monitored is 108 (93.1%). Therefore, loss to follow-up until the end of the study was only 6.9%. (Table 1)

Baseline characteristics of our study subjects are presented in Table 2. All women who underwent cesarean section during the period of study that met the inclusion criteria and had no exclusion criteria were included in the study, regardless of the size of the opening of the cervix and the presence or absence of premature rupture of membranes. Youngest subject was aged 15 years old, the oldest was 40 years old, and most belonged in the 25-29 year age group (65 acceptors, 56%). The number of primiparous and multiparous women were comparable. Most of the newborns weighed between 2,500-3,999 grams (81%), and only 2 women (1.7%) had babies weighing >4,000 grams. History of premature rupture of membranes was present in 23.9% of the women.

Table 1. Monitoring Data.

	M-1	M- 2	M-3	M-4	M-5	M-6
Acceptor	116	116	116	116	116	116
Observed:						
Visit	38 (32.8%)	19 (16.4%)	8 (6.9%)	8 (6.9%)	8 (6.9%)	40 (34.5%)
By phone	23 (19.8%)	1 (0.8%)	2 (1.7%)	2 (1.7%)	0	68 (58.6%)
Total observed	61 (52.6%)	20 (17.2%)	10 (8.6%)	10 (8.6%)	8 (6.9%)	108 (93.1%)

Note: M-1 = postpartum to 6 weeks, M-2 = 6 weeks to 3 months, M-3 = 3 months to 6 months, M-4 = 6 months to 9 months, M-5 = 9 months to 12 months, M-6 = 12 months postpartum.

Table 2. Baseline Characteristics.

Variable (n=116)	n	(%)	mean (SD)	min.	max.
Age (years) :			27.4 (5.26)	15	40
15-19 years	7	6.1			
20-24 years	15	12.9			
25-29 years	65	56.0			
30-34 years	22	18.9			
35 years	7	6.1			
Normotensive	85	73.3	120.35 (7.69)	100	135
Hypertensive			158.38 (14.06)	140	190
140 - 160 mmHg	8	6.9			
> 160 mmHg	23	1.8			
BMI			27.23 (3.68)	19.29	39.33
Gestation age (weeks)			38.5 (2.47)	28	44
preterm	17	14.7			
aterm	95	81.9			
serotinus	4	3.4			
Parity			1.66 (0.79)	1	5
1	57	49.1			
>1	59	50.9			
Birth weight (gr)			2,950 (554)	1,000	4,500
< 2,500 gr	19	16.4			
2,500 - 3,999 gr	95	81.9			
4,000 gr	2	1.7			
Anemia					
Yes (Hb<10 gr%)	62	53.4	11.20 (1.29)	7	14.5
No (Hb>10 gr%)	54	46.6			
PROM					
No	89	76.7			
Yes, <6 hours	12	10.4			
Yes, >6 hours	15	12.9			

Note: $PROM = premature \ rupture \ of \ the \ membrane$

In the 6 months postpartum period, only two acceptors reported complaints of smelly lochia. Similarly, only two acceptors reported presence of pu-

erperal fever. Table 3 summarizes the complaints present at each monitoring period.

Table 3. Complaints at Each Monitoring Period.

	M-1 (n=61) n (%)	M-2 (n=20) n (%)	M-3 (n=10) n (%)	M-4 (n=10) n (%)	M-5 (n=8) n (%)	M-6 (n=108) n (%)
Smelly lochia						
No	59 (96.7%)					
Yes	2 (3.2%)					
Puerperal fever						
No	59 (96.7%)					
Yes	2 (3.2%)					
Vaginal discharge						
No		18 (90%)	8 (80%)	8 (80%)	12 (85.7%)	101 (94.4%)
Yes		2 (10%)	2 (20%)	2 (20%)	2 (14.3%)	7 (6.5%)
Pelvic discomfort						
No	58 (95.1%)	19 (95%)	10 (100%)	16 (88.9%)	14 (100%)	103 (95.4%)
Yes	3 (4.9%)	1 (5%)	-	2 (11.1%)	-	5 (4.6%)
Dysmenorrhea						
No		11 (91.7%)	8 (88.9%)	13 (76.5%)	10 (76.9%)	95 (88.8%)
Yes		1 (8.3%)	1 (11.1%)	4 (23.5%)	3 (23.1%)	12 (11.2%)
Menstrual bleeding						
As usual		10 (83.3%)	7 (77.8%)	14 (82.4%)	13 (100%)	101 (94.4%)
Menorrhagia		2 (16.7%)	2 (22.2%)	3 (17.6%)	<u>-</u>	6 (5.6%)

Note: M-1 = postpartum to 6 weeks, M-2 = 6 weeks to 3 months, M-3 = 3 months to 6 months, M-4 = 6 months to 9 months, M-5 = 9 months to 12 months, M-6 = 12 months post partum.

Follow-up of 108 acceptors of IUD users for 1 year or more shows no incident of expulsion. At the 6-month follow-up, there were three IUD removals reported with two acceptors reporting IUD string to disturb sexual intercourse and one ac-

ceptor wanted to get pregnant again because her baby died. There was only one incidence of unintended pregnancy, which occurs within 12 months of monitoring.

Table 4. Analysis of Expulsion Rate, Discontinuation and Continuation Rate Up to 12 Months Post-Insertion (n =108).

	M-1 (<6 weeks)	M-2 (6 weeks - 3 months)	M-3 (3 months - 6 months)	M-4 (6 months - 9 months)	M-5 (9 months - 12months)	M-6 (12 months)
Expulsion	0	0	0	0	0	0
Discontinuation						
Pregnant	0	0	0	0	1 (0.93%)	1 (0.93%)
Menstrual problem	0	0	0	0	0	1 (0.93%)
Personal reason	0	3 (2.78%)	3 (2.78%)	3 (2.78%)	3 (2.78%)	3 (2.78%)
Continuation rate	108 (100%)	105 (97.22%)	105 (97.22%)	105 (97.22%)	104 (96.29%)	103 (95.37%)

DISCUSSION

IUD insertion technique in this study is different from the first technique introduced by Zerzavy in 1967 . Zerzavy performed suturing on the fundal myometrial wall by making loose knots on the IUD (Birnberg bow) so that the IUD can move freely in the uterine cavity. However, until this study began in 2009 there has been no publication of new scientific developments regarding how to suture IUD on the fundus wall. Furthermore, techniques used by Zerzavy is no longer possible because when suturing through the lower uterine segment incision hole, the needle cannot reach the highest part of posterior fundus wall.

A 1983 research in China by Liu et al performed IUD insertion by suturing through the incision to the posterior uterine wall.¹⁸ Cohort studies in Belgium in 1985 examined transperitoeal insertion of IUD TCu-220 in 82 women who underwent cesarean section. IUD is inserted manually and monitored for up to 12 months. There was no incidence of pregnancy and expulsion rate was found to be 7.7%.¹⁶

A multicenter study in China reported manual stainless steel ring IUD insertion or using ring forceps in elective cesarean section. Expulsion rate obtained at 12-months observation ranged from 4.1 to 5.5%. Pregnancy rate was between 6.1-8.9%.¹⁹

By the hang-up technique applied in this study, the IUD can be placed right in the center of the fundus, and the anchor knot on the crossing arm of the IUD allows fixation of the IUD so it hangs on the uterine fundus wall in a balanced position while still being flexible so that the IUD can move freely to follow the uterine shape changes during involution. In this study, numbers of loss of followup were low (6.9%). Of 116 acceptors who have used the IUD for 1 year or longer, 108 acceptors (93.1%) who were observed until the end of the study period, either by letter or telephone. In the monitoring period M-1 through M-5 (<6 weeks to 12 months postpartum), a low number of acceptors is observed. This is because most of the mothers who delivered in Dr. Kariadi hospital is referred from the district hospitals in Central Java, so that not all IUD acceptors received counseling regarding post-placental IUD insertion since their antenatal examination. These patients only received counseling for IUD insertion when the mother has begun labor. Another factor causing the low monitoring attendance is incomplete records with unclear address, patients who have moved or changed phone number given so they could not be contacted. In addition, most of the acceptors belonged to the low socioeconomic level group and prioritized their time for work. Therefore, when they have no complaints, they will not come for follow-up.

The youngest acceptor was 15 years of age, the oldest was 40 years old, and the acceptors were most commonly in the 25-29 years age group (65 acceptors, 56%). Technical advantages of hang-up technique is because the suture is performed at the fundus so there were less concern for impending expulsion in the future. IUD insertion was applied to all cesarean deliveries without considering diameter of cervical dilatation. Although as much as 23.3% subjects (27 acceptors) experienced premature rupture of membranes where 10.4% subjects (12 acceptors) had amniotic membrane rupture is less than 6 hours and 12.9% (15 acceptors) experienced premature rupture of membranes for more than 6 hours, complaints of puerperal infection symptoms was just observed in 6.4% of subjects. 3.2% subjects (2 acceptors) with a history of smelly lochia and 3.2% (2 acceptors) with a history of puerperal fever in the first follow-up (M-1). During the follow-up period, there were complaints of vaginal discharge, pelvic pain, dysmenorrhea and excessive menstrual blood. However, the complaint was not perceived to be too intrusive and does not result in a request for IUD removal. Several studies have found no significant difference for the risk of infection in women who had immediate IUD insertion during cesarean delivery to women who did not have IUD insertion.^{20,21}

The major problem in the immediate postplacental IUD insertion was the higher expulsion rate compared to the insertion during the interval period. Literature states that the high rate of expulsion depends on the timing of insertion, type of IUD, and IUD insertion techniques.²² Study on 82 acceptors of immediate postplacental insertion during cesarean delivery using CuT-220 done in Belgium in 1984 where IUD was inserted manually as high as possible in the direction of the fundus discovered that in the 12 months observation, there was no incidence of pregnancy while the expulsion rate was 7.7%.¹⁶

A descriptive study in Turkey in 2004 reported the expulsion rate and continuation rate at 1 year

after CuT-380A IUD insertion in 235 mothers after vaginal delivery and cesarean section. IUD insertion using ring forceps was performed both at vaginal delivery (74%) and cesarean section (26%). Combined expulsion rate was 5.1%, 7.0% and 12.3% respectively at 6 weeks, 6 months and 12 months after insertion. In this study, IUD insertion was done when the cervical opening <6 cm.⁷

A study carried out in Brazil in 2005, which compared 19 women who had postplacental IUD insertion after vaginal delivery with 19 women who had IUD insertion after cesarean section. In the vaginal delivery group expulsion rate was 77.8% (14 acceptors) based on clinical and ultrasound examination. Meanwhile, the cesarean group experienced no expulsion. Insertion is done using a ring forceps on the insertion site of the placenta after vaginal delivery and manually through the incision in the lower uterine segment.²³

Research by Celen et al in Turkey on 245 women who underwent cesarean section and IUD insertion using ring forceps showed that on 6 weeks, 6 months and 12 months postpartum follow-up incidence of pregnancy was 0.4% (1 case), expulsion rate was 17.6%, IUD removal due to bleeding/pain occurred in 8.2% of subjects and removal for other medical reasons occurred in 2,4%. Celen et al observed that continuation rate was 81.6% at 6 months follow-up and 62% at the 12 months follow-up.²⁴

A cohort study by Levi et al in 2012 observed 90 women who underwent CuT-380A IUD insertion during cesarean section in 5 hospitals in USA for 6 months. On follow-up, the first visit at 6 weeks after cesarean section showed 48% (43 acceptor) attended the postnatal control, and the IUD was still evident in 32 women (72%) as confirmed by ultrasound or presence of a thread on vaginal examination. However, in the remaining 26% (11 women) the thread could not be found or they did not arrive at the scheduled time for ultrasound examination. Eleven women were contacted by telephone and reported no experience of expulsion. At 6 months postpartum monitoring, 47% of women (42 acceptors) who were interviewed by telephone, reported no expulsion, no IUD removal requests and 32 women (55%) complained of cramps or heavy menstrual bleeding.²⁵

By applying the hang-up technique, the horizontal arm of the IUD is attached to the fundus, so no shift or malposition is expected. Some things that

can cause a change in the position of an IUD are possible loosening of the knot or because of lack of proper technique in making the knot. In this study, there was no expulsion at all stages of monitoring up to 12 months.

After completion of 12 months follow-up, no incidence of perforation caused by IUD insertion was reported. The absence of perforation incidence may be due to the fact that researchers can directly visualize the IUD placement in the fundus and the IUD can be placed manually or assisted by ring forceps. Ultrasound examination of acceptors who came to the clinic did not detect any translocation. Effectiveness of contraception is expressed in Pearl Index, which is the number of unintended pregnancies per 100 acceptors for 1 year of contraceptive use.²² Medical Eligibility Criteria for Contraceptive Use (WHO, 2009) states that the effectiveness of IUD interval insertion is 0.8 for typical use and 0.6 for perfect use.¹²

In our study we observed one acceptor who experienced pregnancy out of 108 acceptors, so the Pearl Index was 0.93 typical use. There were five IUD removal requests, with two acceptors complaining the thread to be very disturbing, one acceptor was pregnant with the IUD in situ, one acceptor wanted to get pregnant because her baby died at the age of 3 days postpartum, and one acceptor complained of excessive menstrual bleeding. Therefore, we obtained the continuation rate to be 95.37%. In a recent study of postplacental CuT-380A IUD insertion using ring forceps in cesarean section delivery in Turkey the continuation rate was 62%. This low survival rate is partly due to the high incidence of expulsion (17.6%) in the 12 months observation.²⁴

CONCLUSION

The study showed the high effectiveness of postplacental IUD insertion during cesarean delivery using hang-up technique with 0.93 Pearl index for typical use. Side effects such as puerperal infection and menstrual problems were relatively low. There was no incidence of expulsion or perforation in this study. Continuation rate was also found to be high (95.37%).

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